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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/476,485	12/30/1999	M. Gabriella Colucci	108.236.119	7906

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
476,485	COLUCCI et al
Examiner	Group Art Unit
	1044

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1 – 61 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1 – 61 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The claims pending are 1-61.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 9-14 and 61, drawn to a member of the FRIL protein family, classified in class 530, subclasses 350 and 370+.

II. Claim 8, drawn to a nucleic acid encoding a FRIL protein, classified in class 536, subclasses 23.1 and 23.6.

III. Claims 15-19 and 49-52, drawn to a method for preserving progenitor cells in vivo and a method of reducing hematopoietic progenitor cell-depleting activity of a therapeutic treatment by separately administering a FRIL protein family member and the therapeutic treatment, classified in class 514, subclass 2+.

IV. Claims 20-32, drawn to a method of isolating progenitor cells by employing plural FRIL protein family members, classified in class 435, subclass 2 and 325+.

V. Claims 33-41 and 56, drawn to isolated progenitor cells, classified in class 435, subclass 325+.

VI Claims 42-48, drawn to a method for preserving progenitor cells ex vivo, classified in class 435, subclasses 2 and 325+.

VII. Claims 53-55, drawn to a method of identifying a progenitor cell, classified in class 435, subclass 7.21+ and 7.24.

VIII. Claims 57-60, drawn to a method of identifying a FRIL family member, classified in class 435, subclasses 7.8 and class 436, subclass 501.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different structures and functions and would not be used together in one method.

Furthermore, in the era of genome sequencing, a nucleic acid per se can be known in the art prior to any knowledge of the nature and function of the encoded protein.

Inventions I and III (as well as IV, VI and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product has uses other than those of the in vivo treatment method of Group III, the ex vivo treatment method of Group VI, the cell isolation method of Group IV or the cell identification method of Group VII.

For example, the FRIL protein product could, be used as an agent in cell cultures, in order to enrich the proportion of progenitor cells therein from which progenitor cell lines could be obtained. Also the FRIL protein could be used to treat an animal in vivo, prior to isolating bone marrow cells therefrom, in order that cultures of bone marrow cells would be enriched in progenitor cells.

Alternatively products other than that of Group I could be used to practice the method of Group III (as well as IV, VI and VII). For example, a monoclonal antibody directed to the glycosylated extracellular domain of an FLT3 receptor could be employed to conduct such methods.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the FRIL protein family member of group I and the identified cell do not have common properties or functions and are not used together, as reagents, in any of the claimed methods.

Furthermore, the cells of Group V could have been obtained without the FRIL family member of Group I - e.g. by using an antibody directed to the glycosylated extracellular domain of an FLT3 receptor.

Inventions VIII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (e.g. a lectin) could have been obtained by another identification process.

It is well known that glycosyl moieties which are recognized by particular lectins or by particular monoclonal antibodies can be shared by glycoproteins on diverse types of cells, e.g.

hematopoietic cells, activated lymphocytes, tumor cells. Thus the FRIL family members that bind to the glycosylated extracellular domain of an FLT3 receptor could have been identified by their binding to other glycoproteins with like glycosylation patterns.

The nucleic acid composition of Group II is not used in any of the methods of Groups III-IV or VI - VIII.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the nucleic acid of Group II and the cell of Group V, do not have common properties or functions; they are not used together, as reagents, in any claimed process.

The in vivo treatment method of Group III and the ex vivo preservation method of Group VI have different steps and would be practiced separately. Further a teaching of one of these methods need not teach or render obvious the other. For example, a teaching of an ex vivo method, could not render an in vivo method obvious since one could not predict whether or not the FRIL protein would reach its intended target in vivo. Groups III and VI are thus patentably distinct.

The in vivo and ex vivo treatment methods of Groups III and VI have no steps in common with the cell isolation and identification methods or the FRIL family member identification methods of Groups IV, VII and VIII, respectively. Groups III and VI achieve

different ends from any of the methods of Groups IV, VII or VIII and are therefore patentably distinct from these.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cell isolation method of Group IV and the cell identification method of Group VII, do not involve common steps and achieve different ends.

For example the cell identification method of Group VII does not require a separation step, as in Group IV. The method of Group VII could be practiced with unseparated cells, such as those present in a histological section or a smear.

The cell isolation and identification methods of Groups IV and VII have no steps in common with the FRIL family member identification method of Group VIII. They use different reagents and achieve different ends. Therefore Groups IV and VII are patentably distinct.

In the event the applicant elects one of Group I-IV or VI-VII the following election of species requirement is stated:

Claims 1-32, 42-55 and 61 are generic to a plurality of disclosed patentably distinct species comprising distinct FRIL family member proteins, such as known lectins or the disclosed proteins Dl-FRIL and PV-FRIL, or the different nucleic acids encoding a particular one these, or methods using a particular one of these. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event GroupV is elected, the following election of species requirement holds.

Claims 33-39, 41 and 56 are generic to a plurality of disclosed patentably distinct species comprising each of the types of progenitor cells recited in the Markush group of claim 39. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Mon.-Thur. from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3704.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 7, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

RESTRICTION ELECTION FACSIMILE TRANSMISSION

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